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October 14, 2003

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Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 "C" Street SW Washington, DC 20204

Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, Leiner Health Products notifies the FDA that it has begun using the following phrases and statements:

Starch Away® Blocks Carbs by reducing Calories form Starchy Foods

Now you don't have to give up bread and pasta.

Starch Away® is a new diet aid that's safe, natural and easy: Just take 1-2 delicious citrus soft chews a few minutes before a meal that contains a "starch" (bread, potatoes, pasta, grain - even French fries contain starch) and you can block the digestion of starch calories.

Starch Away® is also a perfect alternative for people who want to follow an all protein diet, but don't want to give up starch.

Starch Away® is NOT an appetite suppressant or meal replacement. It's a whole new approach to dieting!

Starch Away® contains Phase 2 Starch Neutralizer, an active natural ingredient that inhibits amylase from converting starch to sugar, thereby blocking the body's intake of starch carbohydrate calories. Without the starch-to-sugar conversion, the starch is safely eliminated from the body before it is converted to sugar and can be stored as fat.

on the following product:

Starch Away®

Very truly yours,

Leiner Health Products

William Cochran, Manager of Regulatory Affairs

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